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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,289

10/15/2003

Ivan Osorio

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BANNER & WITCOFF, LTD  
AND ATTORNEYS FOR CLIENT NUMBER 011738  
10 SOUTH WACKER DRIVE  
SUITE 3000  
CHICAGO, IL 60606

EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,289	<b>Applicant(s)</b> OSORIO ET AL.	
	<b>Examiner</b> ALYSSA M. ALTER	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed November 27, 2007 have been fully considered but they are not persuasive. Therefore the claims stand rejected in view of Whitehurst (US Patent Publications 20020013612 A1). The Applicant argues that Whitehurst fails to disclose switching feature. However, as previously stated, Whitehurst does in fact switch between modes, specifically open and closed loop mode. (Please see below for further explanation.)

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-19 and 21-37 stand and claims 38-39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Whitehurst (US Patent Publications 20020013612 A1). Whitehurst discloses a

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system and method for treating mood or anxiety disorders, which is a nervous system disorder, by utilizing an implantable system control unit (SCU), electrodes and a pulse generator for treatment.

As to claims 1, 4, 11, 13-14, 19 and 39, the system is capable of open- and closed-loop operation. Open loop operation does not require feedback, while closed loop operation does utilize feedback. Feedback, in order to modify the monitoring and programming capabilities of the SCU, can be provided by a sensor, patient or clinician. In the event that the feedback is transmitted to a SCU by a patient or clinician through an external component, hand held patient programmer (HHP) 190 or clinician through a clinician programming system (CPS) 192, the external component is modifying the treatment mode and thus creating a closed loop operation. This closed loop treatment operation is considered to be the second treatment mode. When the external component modifies the function of the SCU, the external component is "coupled" to the SCU via telemetry or the first communications channel. In the event that the external component is not sending telemetric signals, the external component is not actively "coupled" to the SCU, and is thus functioning in the open loop operation, which is considered to be the first treatment mode.

Furthermore, as to claims 1, 4, 11, 13-14, 19, 21-22 and 39, Whitehurst discloses on page 7, paragraph 84, "when it is required to communicate with SCU 130, patient 200 is positioned on or near external appliance 220, which appliance contains one or more inductive coils 222 or other means of communication (e.g., RF transmitter and

receiver)". Therefore, the SCU is selectively "coupled" in a closed-loop operation or uncoupled away from the external components in an open-loop operation.

Still further, Whitehurst discloses on page 8, paragraph 92, "external electronic appliance 230 may include an automatic algorithm that adjusts electrical and/or drug stimulation parameters automatically whenever the SCU(s) 130 is/are recharged".

Therefore, Whitehurst discloses the switching between open and closed loop function.

Additionally, Whitehurst discloses on page 8, paragraph 90, "it may alternatively **or additionally** be desirable to use a separate or specialized implantable device to record and telemeter physiological conditions/responses in order to adjust electrical stimulation and/or drug infusion parameters. This information may be transmitted to an external device, such as external appliance 220, or may be transmitted directly to implanted SCU(s) 130". Therefore, since there is two modes of operation, closed loop and open loop, there would necessarily be a mode of switching between them.

In the alternative, although the examiner considers Whitehurst to disclose a switching mode above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a mode of switching between open and closed loop operations in order to enable switching between physician programming and self-reliant operation in order provide the predictable results of modifying the therapy treatment to meet specific patient needs and employ power conservation for the system.

As to claim 2, the programmer is the patient who directly communicates with the SCU via a HHP 190. Additionally, the third treatment mode is the administering of drug stimulation.

As to claims 3 and 5, the programmer is the clinician who indirectly communicated with the SCU by means of the CPS 192 via the HHP 190, as discloses on page 7, paragraph 82. Additionally the HHP 190 functions as a relay module. Additionally, the third treatment mode is the administering of drug stimulation.

As to claims 7 and 26-27, the sensing function or device for the sensing symptoms or other prognostic or diagnostic indicators of mood and/or anxiety disorders is the triggering device that affects at least one of the treatment therapy modes.

As to claims 8, the second communications channel is 246 as displayed in figure 7 between the first external appliance 230 and the other computing means 248.

As to claims 9-10, 12, 23 and 32, the examiner considers the additional module or external component to be the clinician programming device CPS 192, which is capable of communicating with the SCU via the HHP 190. The CPS 192 can also support an additional treatment therapy, such as the administration of drug stimulation.

As to claims 15-16 and 37, the first treatment therapy mode is an open-loop mode, which is equivalent to basic loop recording, and the second treatment therapy mode is a closed-loop mode, which is equivalent to enhanced loop recording.

As to claim 17-18, Whitehurst discloses a system and method for treating mood or anxiety disorders, which is a nervous system disorder, by utilizing an implantable system control unit (SCU), electrodes and a pulse generator for treatment.

2. Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst (US Patent Publications 20020013612 A1) in view of Haller et al. (US Patent Publication 20020013613 A1) for reasons previously made of record. Whitehurst discloses the claimed invention except for the sensing of the patient location. Haller et al. teaches that it is known to use a GPS system to identify the location of the patient, for the purpose of monitoring the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the therapy system as taught by Whitehurst with the GPS system as taught by Haller et al., in order to monitor and provide assistance to the patient in the event the patient is incapacitated and cannot request help.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
Art Unit 3762